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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,664	02/27/2002	Deepak Murpani	RLL-201US	8677
26815	7590	03/02/2005	EXAMINER	
RANBAXY INC. 600 COLLEGE ROAD EAST SUITE 2100 PRINCETON, NJ 08540			WANG, SHENGJUN	
		ART UNIT	PAPER NUMBER	1617

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/085,664	MURPANI ET AL
	<b>Examiner</b>	<b>Art Unit</b>
	Shengjun Wang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 4-30 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-2, 4-20, 25-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2004 has been entered.
2. Claims 1-2, 4-30 are pending, claims 21-24 are withdrawn from further consideration as drawn to non-elected subject matter.

#### ***Claim Rejections 35 U.S.C. 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-2, 4-20, 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term "fast" in claim 1 is a relative term which renders the claim indefinite. The term "fast" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the dissolving speed of the tablet encompassed thereby.

#### ***Claim Rejections 35 U.S.C. 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 4, 6-12, 14, 25, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hancock et al. (WO 97/44028).

8. Hancock et al. teaches a rapid dissolving sublingual formulation of rofecoxib which further comprising croscarmellose, microcrystalline cellulose, lactose monohydrate iron oxide, magnesium stearate, wherein the formulation may be made into tablet by directly compress. The amount of the COX-2 inhibitor in the composition is about 5-125 mg, and 5 to 25 mg in particular. The amount of magnesium stearate is about 0.5 to 1.5% w/w. See, particularly, page, 7, line 5-12, example 2a to 2c, and the claims.

***Claim Rejections 35 U.S.C. 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 5, 13, 15-20, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock et al. (WO 97/44028), in view of King et al.

11. Hancock et al. teaches a rapid dissolving sublingual formulation of rofecoxib which further comprising croscarmellose, microcrystalline cellulose, lactose monohydrate iron oxide, magnesium stearate, wherein the formulation may be made into tablet by directly compress. The amount of the COX-2 inhibitor in the composition is about 5-125 mg, and 5 to 25 mg in

particular. The amount of magnesium stearate is about 0.5 to 1.5% w/w. See, particularly, page, 7, line 5-12, example 2a to 2c, and the claims. Hancock et al. further teaches the composition may further comprise other ingredients such as sweetening agents, flavoring agents, coloring agents. As to tablet composition, any pharmaceutical acceptable excipients may be included. See, particularly, page 6, line 10-30.

12. Hancock et al. do not teach expressly teaches a tablet composition comprising the particular COX-2 inhibitor herein, the particular excipients with the particular amounts herein.

13. However, King et al. teach that making tablet with various known pharmaceutical excipients, including diluents, binder, lubricants, glidants, disintegrants, coloring agents, and flavoring agents (mannitol, aspartame etc.) is well-known in the art. See, pages 1605-1608.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a tablet with rofecoxib according the teaching by Hancock et al., which further comprising those known excipients herein recited. A person of ordinary skill in the art would have been motivated to a tablet with rofecoxib which further comprising those known excipients herein recited because rofecoxib is the preferred COX-2 inhibitor disclosed by Hancock et al. and the particular pharmaceutical excipients herein are well-known pharmaceutical excipients, and the employment of those excipients is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388). Further, optimization of the amounts for each of the pharmaceutical excipients is within the skill of artisan.

***Response to the Arguments***

Applicants' amendments and remarks submitted November 8, 2004 have been fully considered, but are moot in view of the new ground rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Art Unit 1617